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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,371	12/21/2000	Kurt C. Gish	A-69028/DJB/JJD	8631

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,371

Applicant(s)

GISH ET AL.

Examiner

Diana Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-502)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: *Detailed Action*

DETAILED ACTION

1. The Preliminary Amendment of paper no. 5, filed April 17, 2001, and the Amendment of paper no. 11, filed May 23, 2002, have been entered.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5).

This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

Election/Restriction

4. Applicant's election with traverse of Group V, new claims 32-38, in Paper No. 11 is acknowledged.

Applicants' traversal is on the ground(s) that "all of the inventions in the present application can readily be searched without undue burden." This argument has been considered but is not found persuasive. As noted by Applicant, MPEP 808.02 requires that the examiner "must show that the restricted groups have a separate classification, acquired a separate status in the art, or that searching would require different fields of search." In the instant case, such a showing was made in the Restriction of paper no.

7. As discussed in paper no. 7, Inventions I-XIV are drawn to recognized divergent

subject matter and require different searches that are not co-extensive. An explanation of the features of Inventions I-XIV that would necessitate different fields of search (e.g., different structural and functional properties of products; different objectives, reagents and/or process steps in methods, etc.) was also provided. Accordingly, Applicants' arguments are not persuasive. It is also noted that separate classification was established in paper no. 7 for several of Groups I-XIV; accordingly, these groups are properly separated from one another based on more than one of the criteria set forth in MPEP 808.02.

With respect to the separation of Groups V and XIV, it is noted that claims 32-38 as amended (the claims of Group V) are drawn to methods in which nucleic acids are detected, classified in class 435, subclass 6, whereas claim 31 (the claim of Group XIV) is drawn to methods in which protein is detected, classified in class 435, subclass 7.1. The methods have different objectives, require different process steps employing different reagents, and require the detection of molecules having different structural and functional properties. Because Groups V and XIV are classified differently and require different fields of search, examination of both Groups would pose a serious burden on the examiner, and therefore restriction for examination purposes as indicated in paper no. 7 is proper.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 1-6 and 8-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

Art Unit: 1634

generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Specification

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Embedded hyperlinks are found at, e.g., pages 9 and 13.

7. The title of the invention is not descriptive of the subject matter of the elected claims. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 32-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of diagnosing the presence or absence of a breast cancer cell in which increased expression of SEQ ID NO: 1 in a sample from a patient as compared to expression levels of SEQ ID NO: 1 in normal breast tissue is detected as an indicator of the presence of a breast cancer cell, does not reasonably provide enablement for methods in which the detection of SEQ ID NO: 1 or a sequence at least 75% identical thereto determines "the presence or absence" of a breast cancer cell in a sample from a patient. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to methods "for determining the presence or absence of a breast cancer cell in a patient" comprising "detecting a nucleic acid comprising a sequence at least 75% identical to SEQ ID NO:1 in a sample from the patient, thereby determining the presence or absence of the breast cancer cell." It is unpredictable as to whether one of skill in the art could practice applicants' invention in a manner reasonably commensurate with the claims. The specification discloses that SEQ ID NO: 1 was found to be upregulated in a variety of breast cancer tissues samples as compared to a panel of controls that included normal breast tissue (see Example 2 and Figure 3). Thus, given the guidance provided by the specification, one of skill in the art could practice methods of diagnosis in which increased expression of SEQ ID NO: 1 as compared to a normal breast tissue control could be detected as indicative of the presence of a breast cancer cell. However, the teachings of the specification do not suggest that mere detection of the presence of SEQ ID NO: 1 would be indicative of the presence of a breast cancer cell. In fact, the specification discloses that SEQ ID NO: 1 is present and expressed in a variety of tissues, albeit at lower levels than in many breast cancer tissues (see Figure 3 and Example 2). Accordingly, based on the guidance provided by the specification, detection of a breast cancer cell requires detection of the upregulation of SEQ ID NO: 1, rather than mere detection of SEQ ID NO: 1. Further, as the specification discloses that SEQ ID NO: 1 is not upregulated in many breast cancer tissue samples (see Figure 3), the teachings of the specification

indicate that detection of low or absent expression of SEQ ID NO: 1 would not allow one of skill to conclude that a breast cancer cell was absent. Further, with respect to detection of sequences "at least 75% identical to SEQ ID NO: 1" other than SEQ ID NO: 1 itself, it is noted that this language encompasses many thousands of molecules differing from SEQ ID NO: 1 in a variety of ways (e.g., molecules comprising numerous mutations, deletions, and/or additions, splice variants, truncated molecules, etc). However, the specification does not disclose whether any of these other molecules encompassed by the claims are actually found in and/or upregulated in breast cancer cells. Absent guidance from the specification, one of skill in the art may look to the teachings of the prior art for enablement of a claimed invention. In the instant case, the closest prior art reference, Billing-Medel et al (WO 99/02714 [1/1999]), discloses an EST, BS200, that is 99.9% identical to nucleotides 1530-3737 of instant SEQ ID NO: 1 (see entire reference, as well as sequence alignment). Given the almost perfect homology of the two molecules (with only 2 mismatches over 2.2 kb), it would appear to one of skill in the art that the molecule disclosed by Billing-Medel et al constitutes a portion of the molecule set forth by Applicants as SEQ ID NO:1. However, Billing-Medel et al disclose that BS200 is upregulated in breast tissues – including normal breast tissues – as compared to other tissue types; particularly, Billing-Medel et al teach that BS200 was "found more than 7 times more often in breast than non-breast tissue" (see p. 57-58). Billing-Medel et al do not provide any evidence that BS200 is up-regulated in breast cancer tissues as compared to normal breast tissue; rather, Billing-Medel et al's teachings suggest that BS200 is specific to breast tissue, including both normal and

cancerous breast. As applicants have exemplified only a single particular sequence that is upregulated (SEQ ID NO: 1), and as the teachings of Billing-Medel et al indicate that this same molecule and/or closely related molecules may be upregulated in normal breast tissues, it is unpredictable as to whether upregulation of the numerous other molecules (other than SEQ ID NO: 1) encompassed by the claims may actually be detected as indicative of the presence of a breast cancer cell. Further, as neither the specification nor the prior art identify, e.g., a mutation or particular alteration that characterizes molecules encompassed by the claims that are upregulated in breast cancer tissues as compared to normal breast (such that one might differentiate those molecules characteristic of breast tissue from those characteristic of breast cancer tissue), it is unknown as to what molecules, if any, other than SEQ ID NO: 1 actually meet the criteria necessary to practice the claimed invention. Thus, it is unpredictable as to whether any quantity of experimentation would be sufficient to enable one of skill in the art to practice the claimed methods with respect to any sequences other than SEQ ID NO: 1 itself. While the guidance provided by the specification and by the art would enable one of skill in the art to practice methods of diagnosing the presence or absence of a breast cancer cell in which increased expression of SEQ ID NO: 1 in a sample from a patient as compared to expression levels of SEQ ID NO: 1 in normal breast tissue is detected as an indicator of the presence of a breast cancer cell, it would require undue experimentation to make and use applicants' invention in a manner reasonably commensurate with the instant claims. With respect to claim 36, it is further noted that while the claim requires that "the nucleic acid is SEQ ID NO: 1," claim 36 is

not limited to methods in which upregulation of the sequence is indicative of the presence of a breast cancer cell.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-38 are indefinite over the recitation of the language "detecting a nucleic acid....thereby determining the presence or absence of the breast cancer cell." This language does not indicate how detection of nucleic acid allows one to conclude whether a breast cancer cell is present or absent. For example, does the presence of nucleic acid indicate the presence of a breast cancer cell or the absence of a breast cancer cell? Clarification is required.

Drawings

12. It is noted that Applicants' formal drawings have been approved by the draftsperson.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sequence search results are cited to show the sequence identity shared between the BS200 sequence taught by Billing-Medel et al and instant SEQ ID NO: 1.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
August 22, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600